DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35

Public Health Service M1958N

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville MD 20850

AUG 6 1998

**WARNING LETTER**
**VIA EXPRESS**

Mr. Gilles Lauriault
President
Biotronix 2000, Inc.
2185 Michelin
Laval, Quebec, Canada H7L 4S2

Dear Mr. Lauriault:

We are writing to you because on June 30 and July 2, 3, 6, 1998, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving your NeedleSafe™ device and your sharps container, which is made and marketed by your firm.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that you obtained marketing clearance before you began offering your products for sale. The kind of information you need to submit in order to obtain this clearance can be obtained by contacting our Division of Small Manufacturers Assistance (DSMA) at 1-800-638-2041 or through the Internet at http://www.fda.gov. The FDA will evaluate this information and decide whether your products may be legally marketed.

Because you do not have marketing clearance from FDA, marketing your products is a violation of the law. In legal terms, the products are adulterated under Section 501(f)(1)(B) and misbranded under Section 502(o) of the Act. Your products are adulterated under the Act because you did not obtain premarket approval based on information developed by you that shows your devices are safe and effective. Your products are misbranded under the Act because you did not submit information that shows your devices are substantially equivalent to other devices that are legally marketed.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Your devices may be detained upon entry into the United States until the premarket clearance issue is corrected. Federal agencies are advised of the issuance of all Warning Letters concerning devices so that they may take this information into account when considering the award of contracts. Additionally, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. Please include any and all documentation to show that adequate correction has been achieved. If documentation is not in English, please provide an English translation to facilitate our review. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Ms. Carolyn Niebauer, Chief, General Hospital Devices Branch at the letterhead address.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting DSMA.

If you have any questions regarding the contents of this letter, please feel free to contact Ms. Leslie E. Dorsey at (301) 594-4618, extension 115.

Sincerely yours,

James L Woodcock Jr

Lillian J. Gill
Director
Office of Compliance
Center for Devices
and Radiological Health